

This Listing of Claims will replace all prior versions, and listings, of claims in this

application:

**Listing of Claims:**

1. (Original) A method of treatment for the prevention or amelioration of tissue damage in a subject who does not have Wilson's disease to prevent or ameliorate tissue damage, which comprises parenterally administering to said subject a therapeutically effective amount of a copper chelator in an amount ranging from about 5mg to about 1100mg.

Claims 2-83 (Cancelled)

84. (New) The method of claim 1 wherein said copper chelator is parenterally administered to said subject for treatment of a disease, condition or disorder selected from the group consisting of diabetic cardiomyopathy, diabetic acute coronary syndrome, diabetic hypertensive cardiomyopathy, acute coronary syndrome associated with impaired glucose tolerance, acute coronary syndrome associated with impaired fasting glucose, hypertensive cardiomyopathy associated with impaired glucose tolerance, hypertensive cardiomyopathy associated with impaired fasting glucose, ischemic cardiomyopathy associated with impaired glucose tolerance, and ischemic cardiomyopathy associated with impaired fasting glucose, myocardial infarction, ischemic cardiomyopathy associated with coronary heart disease, cardiomyopathy, myocarditis, idiopathic cardiomyopathy, metabolic cardiomyopathy, alcoholic cardiomyopathy, drug-induced cardiomyopathy, ischemic cardiomyopathy, and hypertensive cardiomyopathy, acute coronary syndrome not associated with any abnormality of glucose metabolism, hypertensive cardiomyopathy not associated with any abnormality of glucose metabolism, and ischemic cardiomyopathy not associated with any abnormality of glucose metabolism, cardiac structure damage, coronary artery structure damage, plaque rupture of atheromatous lesions of one or more major blood vessels, systolic dysfunction, diastolic dysfunction, aberrant contractility, aberrant recoil characteristics, and aberrant ejection fraction, microvascular disease, one or more diseases of the vascular tree including disease states of the aorta, carotid, and of the arteries including cerebrovascular, coronary,

renal, retinal, iliac, femoral, popliteal, *vasa nervorum*, arteriolar tree and capillary bed, atheromatous disorders of the major blood vessels including the aorta, the coronary arteries, the carotid arteries, the cerebrovascular arteries, the renal arteries, the iliac arteries, the femoral arteries, and the popliteal arteries.

85. (New) The method of claim 84 wherein said cardiac structure damage is selected from the group consisting of atrophy, loss of myocytes, expansion of the extracellular space, and increased deposition of extracellular matrix.

86. (New) The method of claim 84 wherein said coronary artery structure damage is selected from the group consisting of media layer damage and intima layer damage.

87. (New) The method of claim 84 wherein the plaque rupture of atheromatous lesions of one or more major blood vessels is in one or more major blood vessels selected from the group consisting of the aorta, the coronary arteries, the carotid arteries, the cerebrovascular arteries, the renal arteries, the iliac arteries, the femoral arteries and the popliteal arteries,

88. (New) The method of claim 84 wherein said microvascular disease comprises a disorder of one or more of vessels selected from the group consisting of retinal arterioles, glomerular arterioles, *vasa nervorum*, cardiac arterioles, and associated capillary beds of the eye, the kidney, the heart, the central nervous system, and the peripheral nervous system.

89. (New) The method of claim 1 wherein said copper chelator is administered in a single dose or in divided doses.

90. (New) The method of claim 1 wherein said about 5mg to about 1100mg of said copper chelator is administered per day in a single dose or in divided doses.

91. (New) The method of claim 1 wherein said copper chelator is selected from the group consisting of trientine, a trientine salt, a trientine derivative, a trientine analogue, and a trientine prodrug.

92. (New) The method of any one of claims 1 or 84 to 91 wherein said administration is by a route selected from the group consisting of transdermal delivery, topical application, suppository delivery, transmucosal delivery, inhalation, insufflation, buccal delivery, sublingual delivery, and ophthalmic delivery, injection including subcutaneous injection, subdermal injection, intramuscular injection, depot administration, and intravenous injection including bolus injection or intravenous drip injection, an infusion device including a passive or active implantable infusion device.

93. (New) A delivery dosage unit or dosage formulation comprising a therapeutically effective amount of a copper chelator and pharmaceutically acceptable delivery vehicle, said delivery dosage unit or dosage formulation being capable of delivery into a human subject of more than 10% w/w of said copper chelator upon administration to said human.

94. (New) A delivery dosage unit or dosage formulation comprising a copper chelator and pharmaceutically acceptable delivery vehicle, said delivery dosage unit or dosage formulation being capable of delivery into a human subject of a dosage rate of from about  $0.01\text{mg.kg}^{-1}$  to about  $5\text{ mg.kg}^{-1}$  of said copper chelator upon administration to said human subject.

95. (New) A dosage unit of claim 94 wherein said dosage unit is an oral dosage unit.

96. (New) A dosage unit of claim 95 capable of delivery into a human subject of a dosage rate of from about  $0.01\text{mg.kg}^{-1}$  to about  $3\text{ mg.kg}^{-1}$  of said copper chelator upon administration to said human subject.

97. (New) A dosage unit of claim 96 capable of delivery into a human subject of a dosage rate of from about  $0.01\text{mg.kg}^{-1}$  to about  $2.5\text{ mg.kg}^{-1}$  of said copper chelator upon administration to said human subject.

98. (New) A dosage unit of claim 97 capable of delivery into a human subject of a dosage rate of from about  $0.01\text{mg.kg}^{-1}$  to about  $2\text{ mg.kg}^{-1}$  of said copper chelator upon administration to said human subject.

99. (New) A dosage unit of claim 98 capable of delivery into a human subject of a dosage rate of from about  $0.01\text{mg.kg}^{-1}$  to about  $1\text{ mg.kg}^{-1}$  of said copper chelator upon administration to said human subject.

100. (New) A dosage unit of claim 93 wherein the dosage unit is oral and said more than 10%w/w delivery is of that quantity orally taken that moves from the gut into the systemic circulation.

101. (New) A dosage unit of any one of claims 95 to 100 wherein said copper chelator is selected from the group consisting of a trientine active agent, trientine, a pharmaceutically acceptable salt of trientine, a prodrug of trientine and an analog of trientine.

102. (New) A dosage unit of any one of claims 95 to 101 wherein the delivery vehicle is, contains or is associated with at least one delivery agent to enhance entry to the systemic circulation from the gut of the human subject.

103. (New) A dosage unit of claim 102 wherein the at least one delivery agent is selected from the group consisting of one or more synthetic and/or natural polymer, one or more bioadhesive polymer, one or more passive diffusion agent, one or more active transport agent, and one or more facilitated active transport agent.

104. (New) A dosage unit of any one of claims 95 to 103 wherein the copper chelator is admixed with the delivery vehicle.

105. (New) A dosage unit of any one of claims 95 to 104 that is enteric coated, enteric embedded and/or enteric contained.

106. (New) A dosage unit of any one of claims 95 to 105 being a slow release form.

107. (New) A dosage unit of claim 106 wherein said unit has an enteric coated slow release core.

108. (New) A dosage unit of claim 106 or 107 that involves microencapsulation.

109. (New) A dosage unit of any one of claims 95 to 108 wherein more than 50% of the therapeutically acceptable chelator in less than 12 hours is dissolved from the unit into the gastro intestinal tract.

110. (New) A dosage unit of any one of claims 95 to 109 which is a repeat action dosage form having provision for staged release.

111. (New) A dosage unit of any one of claims 95 to 110 wherein the amount of copper chelator in the dosage unit is less than 300mg.

112. (New) A dosage unit of claim 111 wherein the amount of copper chelator in the dosage unit is less than 250 mg.

113. (New) A dosage unit of claim 112 wherein the amount of copper chelator in the dosage unit is less than 240 mg.

114. (New) A dosage unit of claim 113 wherein the amount of copper chelator in the dosage unit is from 120 to 140 mg.

115. (New) A dosage unit of any one of claims 95 to 114 wherein more than 15%w/w of the copper chelator is capable of being delivered from the gut.

116. (New) A dosage unit of claim 115 wherein more than 20%w/w of the copper chelator is deliverable.

117. (New) A dosage unit of claim 116 wherein more than 25%w/w of the copper chelator is deliverable.

118. (New) A dosage unit of claim 117 wherein more than 30%w/w of the copper chelator is deliverable.

119. (New) A dosage unit or formulation of claim 93 that is parenteral.

120. (New) A dosage unit or formulation of claim 119 wherein the therapeutically acceptable copper chelator is selected from the group consisting of a trientine active agent,

trientine, a pharmaceutically acceptable salt of trientine, a prodrug of trientine and an analog of trientine.

121. (New) A dosage unit or formulation of any one of claims 119 or 120 wherein the dosage unit or formulation is transdermal including a transdermal patch, pad, wrap or bandage capable of being adhered or otherwise associated with the skin of a subject, a topical administration formulation, sublingual, a suppository, an injectable unit or formulation including an intravenous unit or formulation, a subcutaneous unit or formulation, an intramuscular unit or formulation, and/or a depot implantable or depot injectable unit or formulation, a formulation deliverable via the eye, or a unit or formulation that is deliverable from an inhalation device.

122. (New) A dosage unit or formulation of claim 121 wherein at least 20% of the copper chelator amount is deliverable into the systemic circulation.

123. (New) An injectable formulation of claim 122 wherein at least 50%w/w of the copper chelator is deliverable into the systemic circulation.

124. (New) A dosage unit or dosage formulation of any one of claims 93 to 123 for use in a method of any one of claims 1 or 84 to 92.

125. (New) A dosage unit or dosage formulation of any one of claims 93 to 123 when packed with a label or instructions for use thereof in the treatment of a disease, condition or disorder of any one of claims 1 or 84 to 92.

126. (New) A dosage unit or dosage formulation of claim 125 wherein a once a day administration is instructed.

127. (New) The use of a copper chelator and other material or materials in the manufacture of a dosage unit or dosage formulation of any one of the claims 93 to 126.

128. (New) The use of claim 127 when for use in a method of treatment as claimed in any one of claims 1 or 84 to 92.